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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,877	10/10/2003	Todd J. Hewitt	355492-2950	7840

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FOLEY & LARDNER LLP
975 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
BOUCHELLE, LAURA A	
ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/683,877	**Applicant(s)** HEWITT ET AL.	
	Examiner LAURA A. BOUCHELLE	**Art Unit** 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2007*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 17-22* is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-14 and 17-22* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All b)☐ Some * c)☐ None of:
        1.☐ Certified copies of the priority documents have been received.
        2.☐ Certified copies of the priority documents have been received in Application No. _____.
        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date *2/1/08*.
4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/07 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4-6, 11-13, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore et al (US 5662622) in view of McGurk (US 5676659) in view of Keith et al (US 6841214). Gore discloses a microcatheter for infusing embolic agents into aneurysms comprising an inner layer 20 being formed of a lubricious material such as PTFE, a braided wire layer 38, and an outer jacket 22 formed of tubular section of increasing flexibility (Col. 4, lines 39-50).

4. Claim 1 differs from Gore in calling for the inner member to have a first and second layer. Claims 4-6 differs in calling for the wire to be made of Nitinol or stainless steel. McGurk teaches a small diameter catheter being formed of an inner tubular member, a reinforcement layer, and an outer layer, similar to that of Gore, but further including the inner member being

formed of a first lubricious layer formed of PTFE and a second outer layer formed of polyimide to provide the inner surface a lubricious lining to receive fluid and an outer lining to contact the reinforcement member (Col. 5, lines 54-67). McGurk further teaches that the wire braid is formed of Nitinol or stainless steel as is well known in the art (Col. 6, lines 6-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gore to include an inner member having a first and second layer and a braid formed of Nitinol or stainless steel as taught by McGurk to provide a lubricious surface for delivering fluid and a non-lubricious surface for contacting the reinforcement layer.

5. Claim 1 further differs from Gore in calling for the braided wire to have a distal segment of a first pic rate and a proximal segment of a second pic rate which is smaller than the first pic rate. Keith teaches a variable stiffness microcatheter comprising an inner layer, a reinforcement layer, and an outer layer similar to that of Gore, but wherein the pic rate of the wire reinforcement is lower as the proximal end than at the distal end to add flexibility to the distal end (Col. 6, lines 55-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time of intention to modify the device of Gore to include a braid member having a lower pic rate at the proximal end than the distal end as taught by Keith to increase the flexibility of the catheter.

6. Claims 11, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore in view of McGurk in view of Keith. At the time the invention was made, it would have been an obvious matter of design choice to make the pick rate of the wire braid change continuously or stepwise in any number of steps. Applicant has not disclosed that the pick rate changing stepwise serves and advantage of particular purpose or solves a stated problem.

Furthermore, one of ordinary skill would expect applicant's invention to perform equally well with either a continuous or stepwise change in pick rate. Therefore, it would have been prima facie obvious to modify the device of Gore in view of Keith to obtain the inventions specified in claims 11, 12, and 13 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

7. Claim 17 differs from Gore in calling for the polymer jacket to comprise polyamide/nylon at its proximal end. Claim 18 differs in calling for the polymer jacket to have polyether polyamide block copolymer at its distal end. McGurk teaches that the outer jacket layer of the catheter comprises polyimide polyether block copolymer or nylon to provide a soft exterior that will not damage the tissues it enters (Col. 3, lines 30-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gore to have an outer jacket formed of polyimide polyether block copolymer or nylon as taught by McGurk to provide a soft exterior that will not damage the tissues it enters.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gore in view of McGurk in view of Keith as applied to claim 1 above, and further in view of Whalen et al (US 2002/0090339). The teachings above are silent as to the burst strength of the device. Whalen teaches a microcatheter for delivering embolizing compositions to an embolic site wherein the catheter has burst strength of at least 1000 psi to allow the device to deliver the viscous embolizing composition without bursting the catheter (page 5, paragraph 0084). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the

device of Gore to have burst strength of 1000 psi as taught by Whalen so that the catheter can deliver viscous embolizing fluid without bursting the catheter.

9. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore in view of McGurk in view of Keith as applied to claims 1, 4, 6 above, and further in view of Scribner et al (US 6053904). Claim 7 differs from the teachings above in calling for the braid to contain 8 wires. Claim 8 calls for the wires to be elliptical in cross section. Scribner teaches a catheter system comprising braided reinforcement wherein the Braid comprises eight wires to provide the member with increased column support and resistance to buckling (Col. 6, lines 27-34). Scribner also teaches that the wires have an elliptical cross section (Col. 6, lines 20-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gore to include a braid with eight wires having an elliptical cross section as taught by Scribner to add column support and resistance to buckling.

10. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore in view of McGurk in view of Keith as applied to claims 1, 4, 6 above, and further in view of Pray (US 5533987). Claim 9 differs from Gore in calling for the pic rate of the wire braid in its least flexible portion to be less than 1/4 of the pic rate in its most flexible portion. Claim 10 differs in calling for the pic rate to change continuously. Pray teaches a catheter with a braid having a pic count at the most flexible end of about 30-40 pic/in and a pic count at the least flexible end to be about 115-140 pic/in or about 4 times that of the less flexible end so that the catheter gradually becomes less stiff as one moves from one end to the other (Col. 10, lines 3-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gore to have a wire braid as taught by Pray to affect the flexibility of the device.

11. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore in view of McGurk in view of Keith as applied to claim 1 above, and further in view of Azam et al (US 5860963). Claim 20 differs from Gore in calling for the most flexible segment of the jacket to have a durometer of 35 or less. Claim 21 calls for the durometer to be about 35, and claim 22 calls for the durometer to be about 25. Azam teaches a catheter having an outer jacket having a durometer at the softest part 30 of 25 to 40 D to ensure softness sufficient to minimize the chances of damage to the inner surface of the vessels it enters (Col. 3, line 62 – Col. 4, line 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gore to have a durometer as taught by Azam to ensure a softness sufficient to minimize the chances of damage to the inner surface of the vessels it enters.

Response to Arguments

12. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
Art Unit 3763

/L. A. B./
Examiner, Art Unit 3763